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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,929	04/16/2004	Alexander Lai	57657/04-265	1334
22206	7590	01/05/2006	EXAMINER	
FELLERS SNIDER BLANKENSHIP BAILEY & TIPPENS THE KENNEDY BUILDING 321 SOUTH BOSTON SUITE 800 TULSA, OK 74103-3318			SALVOZA, M FRANCO G	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 01/05/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,929

Applicant(s)

LAI, ALEXANDER

Examiner

M. Franco Salvoza

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

2. Claims 1, 3, 6, 14, and 17 have been amended, and claim 11 is canceled. Claims 1-10 and 12-19 are pending and under consideration.

Response to Amendment

The amendment filed 10/114/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 1 has been amended to recite a vaccine for equine influenza virus, comprising: an effective immunizing amount of an isolated DNA, the isolated DNA consisting essentially of an HA1 encoding sequence of a strain of equine-2 influenza virus[[],]; and a pharmacologically acceptable carrier or diluent.

It is not clear from the specification what in particular is being excluded from the amendment from "isolated DNA comprising an HA1 encoding sequence" to "isolated DNA consisting essentially of an HA1 encoding sequence."

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite "consisting essentially of" instead of "comprising."

Based on the amendments one cannot discern the differences between the isolated DNA comprising an HA1 encoding sequence and isolated DNA consisting essentially of an HA1 encoding sequence, and furthermore, what would be affected by the change. One cannot tell what is being excluded by the amendment so it is interpreted as open language such as "comprising." It is unclear which elements are excluded from the isolated DNA by the new claim language, and what has been excluded by the amendment has not been taught, as there is no clear definition provided in the specification. Therefore, the "consisting essentially of" language in the claims is being interpreted as "comprising". See the MPEP § 2111.03.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are drawn to a vaccine for equine influenza virus comprising an effective immunizing amount of an isolated DNA, the isolated DNA consisting essentially of an HA1 encoding sequence of a strain of equine-2 influenza virus, and a pharmacologically acceptable carrier or diluent.

Applicant has argued that the expression of the HA1 segment alone is sufficient to elicit protective immunity and that a much lower dosage of the HA1 vaccine is required to confer protection when compared to a DNA vaccine expressing the full length HA gene.

Applicant's arguments have been fully considered, but are not found unpersuasive. The amended claims do not specifically exclude any other elements or coding sequences that would also materially affect the use of the invention and it is not clear how just the HA1 encoding sequence could materially alter the invention while other added and nondescribed components would not. There is no definition in the specification that would differentiate what is considered to be materially altering to the skilled artisan. The rejection is based on new matter because there is no written support for excluding any elements from the claimed method in the disclosure. Applicant has also not pointed to any disclosure that teaches which elements would alter the basic and novel characteristics of the invention. Therefore, it remains unclear what is to be materially excluded that would alter the invention. There is no teaching in the specification that would differentiate what is considered to be materially altering to the skilled artisan.

The Office is not requiring a list of specific materials that would have to be excluded from the claimed method, but a general teaching of properties that would affect the invention. It is applicant's burden to teach what would materially alter the characteristics of the claimed invention. See *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) and *Ex Parte*

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Hoffman, 12 USPQ2d 1061, 1063-64. With this type of teaching, the skilled artisan would be able to readily discern what would be excluded from the “consisting essentially of” claim language. However, since there is no general teaching of this kind in the specification, the claim remains rejected because it introduces new matter into the disclosure.

Claim Rejections - 35 USC § 102

MAINTAINED

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-7, 9-10 and 13 were rejected under 35 U.S.C. 102(b) as being anticipated by either Olsen et al. and/or Lunn et al.

Applicant argues that the amendments distinguish the invention over the prior art, here, the full length HA gene taught by the references. Applicant also argues that expression of the HA1 segments alone is sufficient to elicit protective immunity and discovered that a much lower dosage of the HA1 vaccine is required to confer protection when compared to a DNA vaccine expressing the full length gene. Applicant further argues that updating the vaccine requires only the replacement of the antigen by inserting the HA1 encoding sequence from a new virus.

Applicant's arguments are considered but found unpersuasive. The claim amendment has not sufficiently described what elements of the isolated DNA are being excluded in the amendment from “comprising an HA1 encoding sequence” to “consisting essentially of an HA1

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encoding sequence.” Therefore, “consisting essentially of” will be interpreted openly as “comprising,” making the prior art of record still anticipatory, and the rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 5, 8, 12 14-15, 16 and 17-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over combinations of Olsen and/or Lunn with various secondary references.

Applicant argues that the pending claims’ amendment distinguishes over the prior art, and further, that in the absence of HA2, synthesized HA1 will not be membrane bound and more HA1 molecules are allowed to be released and taken up by antigen presenting cells to elicit a stronger immune response.

Applicant’s arguments are considered but found unpersuasive. As noted above, the claim amendment has not sufficiently described what elements the isolated DNA are being excluded in the amendment from “comprising an HA1 encoding sequence” to “consisting essentially of an HA1 encoding sequence.” Therefore, “consisting essentially of” will be interpreted openly as “comprising,” making the prior art of record still anticipatory, and the rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


M. Franco Salvoza
Patent Examiner


JAMES HOUSEL 12/26/05
SUPERVISORY PATENT EXAMINER
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